

Philips PCR Eleva 1.2 Special 510(k) Submission

December 21, 2009
Update 01**510(k) Summary****Type of submission:** Special 510(k)

JAN - 8 2010

Name and Address of manufacturer:

Philips Medical Systems DMC GmbH
Röntgenstrasse 24-26
D-22335 Hamburg
GERMANY
Establishment registration number: 3003768251
Owner/Operator number: 1217116

Submitter:

Philips Medical Systems
22100 Bothell Everett Highway
Bothell, WA 98041-3003
Establishment Registration No.: 1217116
Contact: Lynn Harmer
425-487-7312

Device Identification

Trade Name: 1.2	PHILIPS Computed Radiography (PCR) Eleva
Common names:	Computed Radiography System Picture Archiving and Communication System
Product Code:	LLZ Radiological Image Processing System 21CFR 892.2050
Subsequent Product Codes:	IXW Automatic Radiographic Film Processor 21CFR 892.1900
	LMA Radiological Image Digitizer 21CFR 892.2030
Classification:	Class II
Review Panel:	Radiology

Predicate device:

Device Name(s):	Philips Computed Radiography (PCR) 5.2
Product Code:	LLZ
Regulation Number:	21CFR 892.2050
Common Product Name:	Automatic Radiographic Film Processor
510(k) Number:	K964124

Basis for the Submission

Multiple modifications to PCR 5.2 leading to PCR Eleva Version 1.2

Indications for Use

The PCR Eleva System is a digital film processing system for reading and then digitizing X-ray images from reusable imaging plates which have been exposed in conventional radiographic examination devices. The digitized X-ray images can then be viewed, stored, post-processed and printed. The PCR Eleva system can be used in all conventional RAD/RF examination situations, except for mammography. PCR is suitable for routine RAD exams as well as specialist areas, like intensive care units, trauma departments and pediatric departments.

Description of the System

A PCR Eleva consists of one or more workspots with PCR Eleva Software and one or more image plate readers. All components are connected via standard ethernet. The system complies with the ACR/NEMA DICOM Version 3 Digital Image Communication in Medicine Standard.

Imaging plates are exposed via conventional X-Ray devices. The imaging plates used in PCR systems are coated with a luminescent material which acts as an x-ray detector. It stores the x-ray image in the form of excited charge carriers. An exposed imaging plate is loaded into the image reader of the PCR Eleva system and the image stored on the imaging plate is scanned with a laser and converted to digital data. The digital X-ray image data is then routed to the Eleva workstation for image processing, viewing, storing and/or printing to film if the workstations are connected to a compatible laser imager. The Eleva Workspot is also used for the scheduling of patients and exams. The Eleva Workstation consists of a PC, a keyboard, a monitor, and an optional bar-code reader.

Summary and results of nonclinical tests

Modifications to the requirements of the predicate device were traced within the design control process and assessed according to the FDA guideline "Deciding When to Submit a 510(k) for a Change to an Existing Device". Verification and validation tests were performed on the complete system relative to the requirement specifications and risk management results, specifically including software verification, validation and DICOM conformance testing. Corresponding test results are included in this submission. All acceptance criteria for a product release according to our product release policy are met.

Based on the test results Philips Medical Systems believes that PCR Eleva 1.2 is at least as safe and effective as the predicate device.

Conclusion

There have been changes that legally require Philips Medical Systems GmbH to submit a 510(k). This includes a change in the software architecture in order to combine different software applications, and the implementation of a new user interface.

Other modifications are not of such significance that a 510(k) would be required. This includes some improvement of certain functionalities.

None of these modifications lead to a change of the indications for use or alter the fundamental scientific technology or introduce a fundamentally new scientific technology. Therefore it has been concluded that a Special 510(k) is appropriate for this type of submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn T. Harmer
Senior Manager Regulatory Submissions
Philips Medical Systems North America Co.
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

JAN - 8 2010

Re: K093355

Trade/Device Name: PHILIPS Computed Radiography (PCR) Eleva 1.2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 21, 2009
Received: December 23, 2009

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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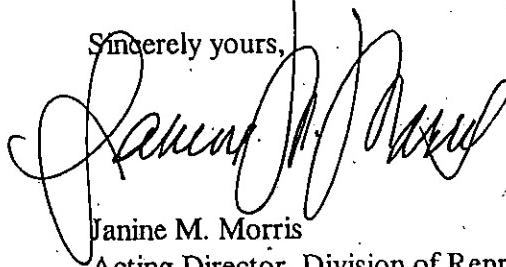
device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803); please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Philips PCR Eleva 1.2 Special 510(k) Submission

October 16, 2009

Indications for Use

510(k) Number (if known): *K093355*Device Name: **PHILIPS Computed Radiography (PCR) Eleva 1.2****Indications For Use:**

The PCR Eleva System is a digital film processing system for reading and then digitizing X-ray images from reusable imaging plates which have been exposed in conventional radiographic examination devices. The digitized X-ray images can then be viewed, stored, post-processed and printed. The PCR Eleva system can be used in all conventional RAD/RF examination situations, except for mammography. PCR is suitable for routine RAD exams as well as specialist areas, like intensive care units, trauma departments and pediatric departments.

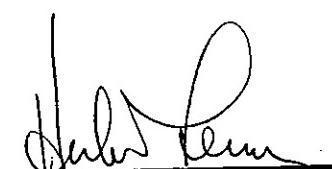
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices510(k) Number K093355

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